

TB Management in Bahir Dar, Ethiopia

- Are we doing things right?



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Key abbreviations

AFB	acid fast bacilli
ART	antiretroviral therapy
CDR	case detection rate
CPT	co-trimazole preventive therapy
CR	cure rate
CXR	chest x-ray
DOTS	directly observed treatment short course
EC	Ethiopian calendar
EPTB	extra pulmonary tuberculosis
FMoH	Federal Ministry of Health
HBC	TB high burden countries
HC	health center
MDR-TB	multi drug resistant tuberculosis
MTB	<i>Mycobacterium tuberculosis</i>
NTPs	National TB Control Programmes
PTB	pulmonary tuberculosis
ss+PTB	sputum smear positive pulmonary tuberculosis
ss-PTB	sputum smear negative pulmonary tuberculosis
TB	tuberculosis
TSR	treatment success rate

Abstract

Background

Ethiopia is ranked number seven among the 22 high burden TB countries (1). The Ethiopian national guidelines for the combined management and technical handling of TB, TB/HIV and leprosy, is found in a standardized manual distributed by WHO (2). Our main objective was to assess the implementation of DOTS in Bahir Dar in means of following the national guidelines in the manual of 2008.

Methods

The study was conducted as an operational research, where we looked at TB registrations in the time period 2008-2010 at three different health facilities in Bahir Dar town, retrospectively.

Results and discussion

The study includes a total of 3,343 TB patients. The amount of ss+PTB patients was low (totally 16.7%), while the numbers of EPTB patients was high (totally 45.9%). The treatment success rate in 2010 was overall 74.8%. At the hospital it was only 60%, contributed by a low registration of treatment outcome (almost 30%) and 10% deaths. In 2010, totally 82% of the TB patients were tested for HIV as recommended and 35% were found HIV positive; much more the national average of 15%. The TB registration was sometimes incomplete and inconsistent.

Conclusions

We generally found that they did a good job, and that they were improving e.g. in offering the recommended HIV testing of TB patients. However, the global target for treatment success rate was not yet achieved, and the data quality showed possibilities for improvements. This might be done by further operational research, regular supportive supervision from the DHO and health workers training in DOTS.

1. INTRODUCTION

1.1 Definition of tuberculosis

Tuberculosis (TB) is an infectious disease, mainly caused by the acid fast, rod shaped bacillus *Mycobacterium tuberculosis* (MTB), rarely by *Mycobacterium bovis* or *Mycobacterium africanum*. The infection is mainly transmitted from sputum smear positive pulmonary TB (ss+PTB) patients, who discharge droplets containing the bacterium when coughing, sneezing or talking (3;4). The risk of transmission is based on the degree of exposure (e.g. duration of time, proximity), how contagious the source is (e.g. smear status and degree of cavitation), and the vulnerability of the exposed (5).

In most cases (90-95%), the MTB is eradicated or kept suppressed by the immune system of the infected as a latent TB infection. Only, 5-10% develops an active disease (primary infection). **Pulmonary TB (PTB)** constitutes the majority of TB cases (85%), and may be divided into the subgroups **sputum smear positive (ss+)** and **sputum smear negative (ss-)** depending on detectable bacteria in sputum or not. The infection may also spread to other organs, causing **extra pulmonary TB (EPTB)** (2).

PTB typically presents with productive cough, persisting for more than two weeks. It may be blood stained, and the patient may have chest pain and shortness of breath. The symptoms of EPTB vary according to the infected organ. General symptoms of illness are usually also present, and include weight loss, intermittent fever, night sweats, malaise and loss of appetite. (2;3;5) However, the symptoms are often mild for months, leading to delay in health care seeking and prolonged transmission of the infection (6).

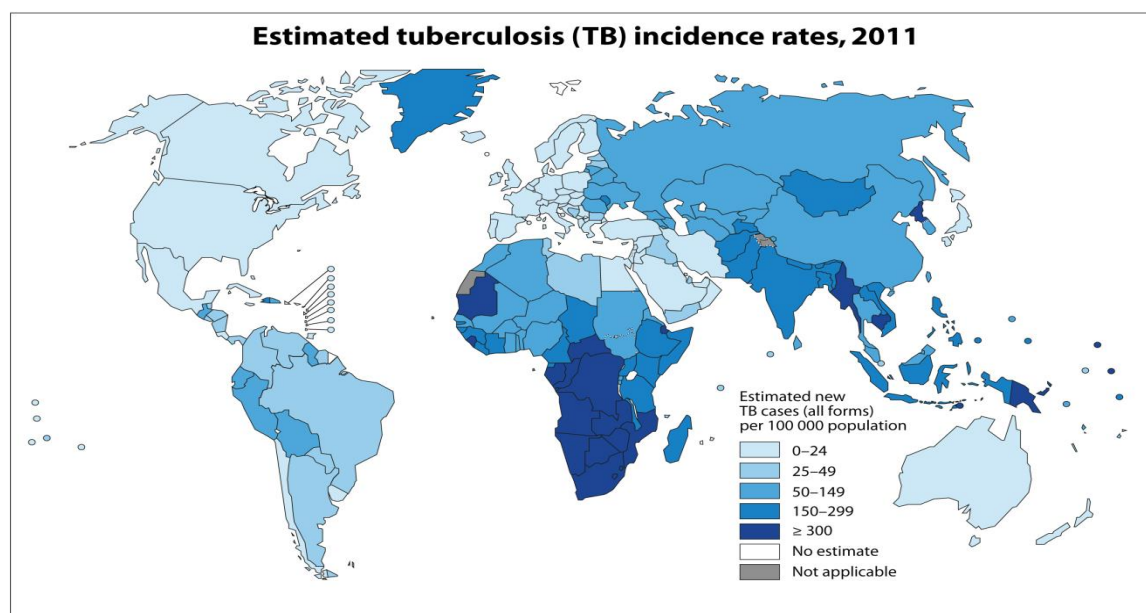
According to WHO guidelines, the recommended diagnostic tool for confirming PTB in Ethiopia is sputum microscopy, which detects acid fast bacteria (AFB). Other diagnostic tools are chest x-ray (CXR), AFB culture (which is expensive, complex and takes several weeks, but can be used to confirm ss-PTB and EPTB), and histo-pathology (rarely used in Ethiopia due to scarcity of pathologists) (2).

Anti-TB treatment lasts for 6-8 months divided into two phases. **The intensive phase** includes the initial 8-12 weeks. For new patients it consists of a drug combination of Rifampizine (R), Isoniazid (H), Pyrazinamide (Z) and Ethambutol (E) which the patient must collect every day (except Sundays), and swallow under direct observation by a health worker.

Normally, the bacilli of the sputum are reduced quickly, and the patient is considered non-infectious at the end of this phase. This is controlled by a sputum smear examination after 2 months (2). In the following months, **the continuation phase**, the drugs are collected regularly and administered at home. The new TB cases should be treated with 6 months of EH according to the 2008 guidelines (2), and 4 months of RH according to the 2012 guidelines (7).

1.2 Global TB burden

According to WHO, about 2 billion people or one-third of the world population, is infected by TB. In 2011, the estimated new cases of TB were 8.7 million (137 per 100,000), and the prevalence was 12 million cases (170 per 100,000). The mortality rate was 20 per 100,000 people, which equals 1.4 million deaths. This makes TB the second most common infectious cause of death after HIV. TB is found all over the world, but mostly affects the low-income countries, where more than 95% of the TB cases and deaths are found. Twenty-two countries called high burden countries (HBC), account for 80 % of the cases. Asia has the highest incidence, constituting about 60% of the new cases. With more than 260 cases per 100,000 inhabitants, Sub-Saharan Africa, however, holds the highest burden per population (1;6).



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Source: *Global Tuberculosis Report 2012*. WHO, 2012.

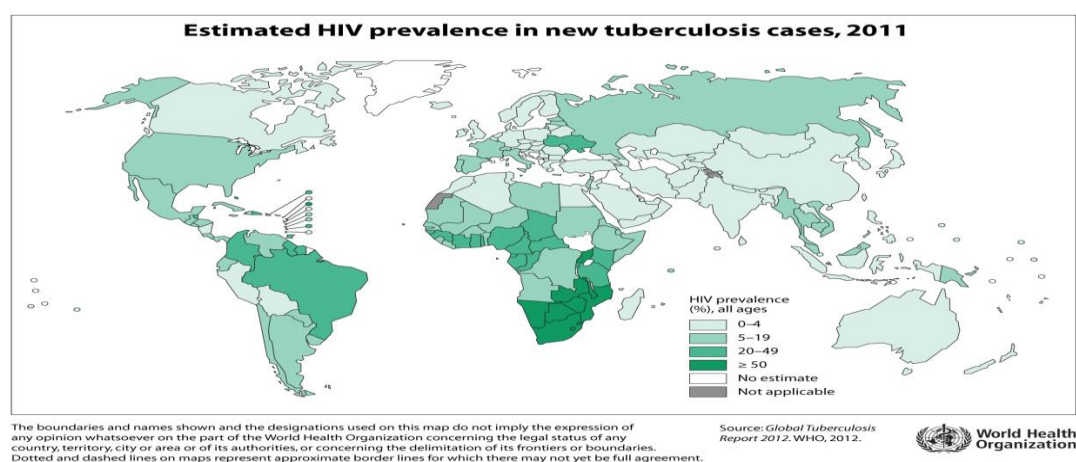


(8)

1.3 Factors increasing the TB burden

Factors increasing the burden of TB may be divided into contributing factors which contributes to an environment for TB to thrive and spread, and risk factors which triggers progression from infection to an active TB disease (4). Increased population, urbanization, and poverty, are some of the most important contributing factors. These facilitate the spread of the infection by favoring undernourishment, and poor living and work conditions with crowding and poor ventilation. These conditions may be maintained by political instability, war and social injustice. Increased migration leads to spread of TB. Especially the forced movement of refugees, as more than 80% originate and remain in high burden countries. These groups, as well as the homeless, are groups deemed difficult to treat as the treatment requires an extended duration and direct observation (4;9;10).

Since the 1980s, HIV and TB together, have constituted a big challenge in many countries; both diseases make the patient more susceptible for infection with the other pathogen, and both speed the process towards disease. Worldwide, more than two-thirds of the 34 million HIV positives have a TB co-infection, the largest proportion is seen in Africa. TB is known as the leading cause of HIV-related morbidity and mortality. Of the estimated 8.7 million new TB patients in 2011, 1.1 million (13%) had a HIV co-infection. And of the 1.4 TB deaths, 430,000 were HIV patients. Worldwide, most HIV/TB-related deaths are among men, but in Africa it mostly occurs among women (1;11). Depending on the HIV-induced immune suppression, HIV-seropositive individuals have 9-16 times risk of developing TB (10), and 21-34 times risk of developing active TB from latent TB (11).



(12)

Drug resistance also contributes to the resurgence of TB, especially in Eastern Europe and Central Asia. Multidrug-resistant TB (MDR-TB) is caused by bacteria that do not respond to, at least, Isoniazid and Rifampicin. It is treatable, but the treatment involves use of second-line drugs, lasts for 2-3 years, and is costly and not always available. Extensively drug resistant TB (XDR-TB) is a bacterium resistant to all currently used TB drugs. The development of these bacteria, are facilitated by inappropriate treatment; incorrect use, poor quality anti-TB drugs and re-infection from fellow patients during treatment (6). In 2011, MDR-TB was estimated to affect 3.7% of all new cases and 20% of previously treated TB (1). Among pulmonary TB patients, 310,000 MDR-TB cases were notified in 2011. Of these, 60% were found in India, China and Russia (6).

Risk factors include all factors that reduce immunity and make a person more susceptible to TB. Some of the most important are malnutrition, underlying systemic diseases (e.g. diabetes and cancer), immune suppression (HIV, use of corticosteroids, transplantation etc), substance abuse, low body weight, age and gender (10). In low-income countries, the highest prevalence is seen among adolescents and young adults due to new infection. In the wealthier countries most infected are found in the higher age groups due to reactivation. Men are more affected than women. This might be explained by more frequent TB exposure in their environment (4;10).

1.4 Prevention and control of the global TB burden

The MTB was discovered by Koch in 1882, introducing a new bacteriological focus in the battle against TB. During the following century, isolation of TB patients as well as improved socioeconomic conditions and living standards, led to a decrease in TB mortality in most industrialized countries. After the development of the Bacille Calmette Guérin (BCG) vaccine and the first anti-TB drugs, TB was declared a priority by WHO in 1947. A TB section was established, and based on i.e. mass vaccination and x-ray screening of the population. It assisted governments in creating vertical control programs that reduced the TB incidence in industrialized countries. However, this improvement was not seen in the low-income countries, and in the early 1990s, the problem grew larger due to emergence of HIV, MDR-TB etc (9).

This aggravated situation, called for a new global TB control initiative. In 1991, two global TB targets were set by the World Health Assembly (WHA) for PTB+: a detection rate

(estimated ratio of ss+PTB detected/cases estimated to exist) of 70% and a treatment success rate (numbers of ss+PTB cured and treatment completed/cases notified) of 85% by year 2000. In 1993, WHO declared TB “a global health emergency”. One year later, they launched a new recommended approach for TB control, called Directly Observed Treatment Short-course (DOTS) strategy. This strategy ensures the identification and cure of infectious TB patients by use of a standardized drug combination (1;2;9). The strategy has five key components:

1. *Government commitment to ensure sustained and comprehensive TB control activities, increase human and financial resources and make TB control a nationwide priority;*
2. *Case detection by sputum smear microscopy among symptomatic patients self reporting to health facilities;*
3. *Standardized short-course chemotherapy using regimens of six to eight months, for all diagnosed cases of tuberculosis under proper case-management conditions, including direct observation of treatment;*
4. *Regular, uninterrupted supply of all essential anti-tuberculosis drugs and laboratory supplies;*
5. *Standardized recording and reporting system that allows assessment of case finding and treatment result for each patient and of the tuberculosis control programme performance overall (2).*

DOTS is centered on the direct observation of drug intake, which means that a health worker has to watch the TB patient taking each dose. This is important to

- *Ensure that patients take the correct treatment regularly;*
- *Notice rapidly when a patient misses a dose, find out why, and solve the problem;*
- *Monitor any problem that the patient may experience with the disease, the treatment or other condition (2).*

The strategy slowly expanded, and in 2008 DOTS was implemented in 182 countries. It helped countries develop national TB control programmes (NTPs), and is the major reason of the progression in TB control seen in the former decade. However, the TB situation was further challenged by the association between TB and HIV, drug resistance etc. This called for a revision of DOTS, and in 2006 the Stop TB Strategy was introduced by WHO. It compromises these six components (2;7;9):

1. *Pursue quality DOTS expansion and enhancement, improving case-finding and cure through an effective patient-centered approach to reach all patients, especially the poor.*
2. *Address TB/HIV, MDR-TB and other challenges, by scaling up TB/HIV joint activities, DOTS-Plus, and other relevant approaches.*
3. *Contribute to health system strengthening by collaborating with other health programmes and general and financial resources for implementation and impact evaluation, and in sharing and applying achievements of TB control.*
4. *Involve all care providers, public, non-governmental and private, by scaling up approaches based on a public private mix, to ensure adherence to the International Standards for TB Care.*
5. *Engage people with TB and affected communities to demand, and contribute to, effective care. This will involve scaling up community TB care; creating demand through context specific advocacy, communication and social mobilization; and supporting development of a patients' charter for the TB community.*
6. *Enable and promote research for the development of new drugs, diagnostics and vaccines. Research will also be needed to improve programme performance (2).*

DOTS remains the cornerstone in this strategy, but it also puts further focus on the challenges of TB-HIV co-infection and MDR-TB. It states that TB-HIV collaboration should be increased, all TB patients should routinely be tested for HIV and vice versa, and all HIV patients should be given antiretroviral- (ART), Co-trimoxazole-(CPT), and preventive isoniazide therapy. The goal of this strategy was i.e. to meet the Millennium Development Goal 6 (MDG6) set for 2015: to halt and begin reverse the incidence of TB by 2015. Also, to meet the target of the Stop TB plan 2006-2008: to reduce the numbers of TB deaths to 50% compared to 1990, and eliminate TB as a public health problem by 2050 (1;13) (<1 case per million population (13)). The updated version of this global plan; the STOP TB plan 2011-2015, also includes targets of 90% treatment success rate and a laboratory strengthening (13;14).

The intensified efforts to reduce the TB burden during the last twenty years, has to some degree shown promising results, but challenges remain. An estimated 51 million people have been successfully treated for TB between 1995-2011. Since 2002, the global incidence rates have been falling, and the case notification rates have declined since 2006, fulfilling the MDG

6 to halt and reverse TB incidence. However, the reduction is slow, and between 2010 and 2011, it was only 2.2%. This is too slow to reach TB elimination by 2050 (1;9).

The global mortality rate has declined 41% between 1990-2011. If the current rate is sustained, the target of 50% reduction by 2015 may be reached in all regions except in Africa. Case notification is also known to be low; of an estimated 8.7 million new TB patients, only two-thirds, or 5.8 million, were reported in 2011. Due to the integrated HIV-TB service, an estimated 1.3 million lives were saved from 2005 to 2011. However, only 180,000 HIV patients received prophylactic isoniazid treatment in 2010 (1;9).

1.5 TB in Ethiopia and Bahir Dar

Ethiopia is located east in Sub Saharan Africa, and th capital is Addis Ababa. The country is boarded by Eritrea to the north, Somalia and Djibouti to the east, Kenya to the south, and Sudan and South Sudan to the west (15). It is administratively divided into nine ethnically based regional states (*killil*) and two city administrative councils. These are further divided into 800 districts (*woredas*) and around 15,000 *kebeles* (15;16). According to WHO's estimation, Ethiopia has a population of 85 million people (17), making it the second-most populous African country after Nigeria. The population growth rate is 2.9% (15).



Map of Ethiopia (15).

The Ethiopian health status is relatively poor. The population is mainly young; 44 % < 15 years, and only 3% over the age of 65 (18). Life expectancy in 2010 was 53 years for men and 56 years for women (19;20). The mortality rate for children under five years was 106 per 1000 live births (20). Preventable communicable diseases and nutritional disorders are still the main health problems (18).

TB is a major challenge, and Ethiopia is ranked number seven among the 22 HBC. According to WHO, there were an estimated 220,000 (258 per 100,000) incident cases (including HIV-positives) in 2011, and the TB prevalence (all forms) was 200,000 (237 per 100,000). The

mortality rate (excluding HIV-positives) was 18 per 100,000 persons, which equals 15,000 deaths (1;17). In 2011, 159,017 TB cases were notified in Ethiopia, estimated as a case notification rate of 72%. Among these, 154,396 were new cases; 49,594 (32%) ss+PTB cases, 52,967 (34%) ss-PTB cases, 2,530 (2%) had unknown sputum smear status, and 49,305 (32%) were EPTB cases. Retreatment cases represent about 2.9% (4,621 cases) of the total TB cases notified (17). The treatment success rate for new PTB+ patients in 2010 was 83% (1).

The male: female ratio among the Ethiopian ss+PTB patients was calculated to be less than the global in 2011; 1.2 vs. 1.7 respectively. About 75% of the TB patients are in the age group 15-54 years, which means the most productive age group. This is an obstacle to the socio-economic development (2). Children under 15 years, contributed 10.5% of the new TB cases in the country (17).

The HIV prevalence in Ethiopia was estimated as 1.5% in 2011 (4.2% for urban area, 0.6% for rural) (1). According to the Ethiopian report of 2009/2010 to the FMOH, the amount of HIV positives screened for TB was about 79%; and of these 11% were diagnosed with active TB. Only 45% of TB patients had been tested for HIV, and 15% were found HIV positive (21). However, the number was 8% according to WHO in 2011. The burden of MDR-TB in 2011, was estimated as 12% (550 patients) of retreatment cases, and 1.6% (1,700) of the new TB cases (17).

Bahir Dar is a town located in the Amhara Region, North West in the country where TB is known for being prevalent. In 2009/2010 there were 1,813 TB patients reported to the Regional Health Bureau, while in 2010/2011 the number was reduced to 1,134 TB patients. However, these numbers may not include reports from all health facilities in Bahir Dar. The town is also known for being a hot spot for HIV with an estimated prevalence of 13.8 in 2005, based on antenatal care data (22).

1.6 TB control efforts in Ethiopia and Bahir Dar

The national Ethiopian work to control TB began in the 1960s with the establishment of TB centers and sanatoriums in three urban areas. The Central Office (CO) of the National Tuberculosis Control Programme (NTCP) was established in 1976. A standardized TB prevention and control programme incorporating DOTS, was started as a pilot within Oromia Region in 1992. Later, the DOTS strategy was implemented in the whole country and the global targets for TB control were embedded. In 1994, it was decided to combine the national

efforts to control TB and leprosy. The National Tuberculosis & Leprosy Control programme (NTLCP) was subsequently established under leadership of the CO. In 2000, the former Epidemiology/AIDS Department of the Ministry of Health (MoH) was reorganized, and the NTLCP was accommodated, making the control activities a responsibility of the general health service. Later, the WHO Stop TB Strategy has also been implemented in the TB control programme. The TB prevention and control programme is implemented at all levels of the health facility, and is guided by a five year TB strategic plan. Today, the national TB control program has reached 100% geographical coverage, and 92% of the public health facilities offer DOTS. However, there is an ongoing increase in the numbers of public and private health facilities, and the programme emphasizes the need to scale up the access of DOTS in line with this (2;21).

Administratively, there is one national TB program manager monitoring a team of 11 TB programme officers. These work in close contact with the Regional Health Bureaus to ensure implementation of the national TB policies at regional level. Each region has a TB and Leprosy Unit led by a Regional TB coordinator who oversees the TB work in the *woredas*. On average, the *woredas* has one health center and five satellite health posts. To optimize the case detection and treatment, the program also engages the private health facilities and health extension workers on the grass root level. The TB diagnosis relies on sputum smear microscopy, which is available at all health centers and hospitals. Culture diagnosis, is only possible at six laboratories, including one in Bahir Dar. Possibilities for fine-needle diagnosis etc, is so far limited, and the capacity to treat MDR-TB patients is limited to two referral hospitals (2;21).

The national guidelines for the combined management and technical handling of TB, TB/HIV and leprosy, is found in a standardized Ethiopian manual distributed by WHO. At the time we conducted our operational research, the edition of 2008 was in use, and hence it is used as reference in our discussion. However, the manual was revised in 2012, and now includes improvements like extended use of local health posts and a different drug combination in the continuation phase (2;7).

The manual states that the general objectives of the NTLPC are:

1. *Interrupt transmission of the infections;*
2. *Reduce morbidity, mortality and disability;*
3. *Prevent emergence and spread of drug resistance;*

- 4. Reduce burden of TB among people living with HIV;*
- 5. Reduce HIV burden among TB patients (2).*

The basic strategies to reach the objectives are:

- 1. Early case detection*
- 2. Adequate chemotherapy*
- 3. Provision of comprehensive & standard patient care*
- 4. Enhanced case management*
- 5. Accurate Monitoring and Evaluation (M & E) of program performance*
- 6. Community participation (2).*

The most cost effective anti-TB initiative, is preventing transmission of TB by identification of ss+PTB patients (by early case detection and diagnosis) and cure through standardized chemotherapy (which renders them non-infectious and cuts the chain of transmission). Case finding strategies include:

- 1. Identification of suspects among patients who present on their own initiative at health facilities or in the community;*
- 2. Proper diagnosis through examination of sputum of patients with symptoms suggestive of TB;*
- 3. Promotion of awareness in the community, amongst the medical staff and the community workers regarding respiratory symptoms, notably persistent cough for 2 weeks or more, and the need to obtain and examine 3 sputum specimens for the diagnosis of TB;*
- 4. Contact screening: examination of household contacts of smear-positive TB patients; irrespective of the duration of cough;*
- 5. Intensified TB screening in high-risk groups (2).*

In Bahir Dar, there is one public hospital and several public health centers which all offer DOTS service. The numbers of private health centers have increased during the last years, and most have implemented DOTS since 2007. All the health centers offer microscopic examination. Culture diagnosis is offered at a laboratory close to the hospital, but the use is limited. The data at the different health facilities are compiled and sent to the Bahir Dar District Health Office, which report the numbers to the Regional Health Bureau.

1.7 Rationale for the study

WHO's Stop TB strategy is implemented in Ethiopia through the National Tuberculosis & Leprosy Control programme. This strategy facilitates research in order to improve TB programme performance. Operational research is used by the programs itself, to control if they are producing the expected results and hence if they are “doing things right”. Such studies have not been conducted in the Ethiopian town Bahir Dar. We wanted to contribute to this by looking at the TB register books kept at the health facilities retrospectively.

2. OBJECTIVES

2.1 General objective

To assess the implementation of DOTS in Bahir Dar town in means of following the national guidelines given in the standard TB manual of 2008 in Ethiopia.

2.2 Specific objectives

1. To determine and evaluate the age and gender distribution of TB patients in Bahir Dar.
2. To describe and assess the case notification of TB patients in Bahir Dar.
3. To describe the conversion rate after 2 months of anti-TB treatment in Bahir Dar.
4. To evaluate the treatment outcome of TB patients in Bahir Dar.
5. To assess the success rate for each category of TB patients in Bahir Dar.
- 6 To calculate and evaluate the HIV prevalence among TB patients
7. To describe the practice for weight recording of TB patients during treatment.

3. METHODOLOGY

3.1. Study area

The study was conducted in Bahir Dar, the capital of the Amhara Region in Ethiopia. Geographically, the city is to be found on the south western side of Lake Tana, the largest lake in the country and the “source” of the Blue Nile. In 2011 (2003 EC) Bahir Dar had a population of 255,779 (from Annual Health Service Report, Amhara Regional Health Bureau, Bahir Dar, Ethiopia).

Bahir Dar has one main public hospital, Felege Hiwot Referral Hospital (FRH), and several health centers, health post and private clinics. Bahir Dar Health Center (HC) is the oldest and largest public health center in Bahir Dar. Han HC is a relatively new public health center, but is smaller. All the three mentioned health facilities are practicing the DOTS strategy.

3.2 Study design

Our study is a retrospective data audit. We were trying to compare what has been accomplished in relation to the standard TB control manual. Observation was done to collect relevant data besides the record review.

3.3 Study population

The study population consists of all TB patients belonging to and noted in the TB registration books in Bahir Dar HC, Han HC and FRH.

3.4 Time period

The data is from a three year period from 2008 to 2010. In Ethiopia they have an own calendar. “The Ethiopian Calendar” (EC) has twelve months with 30 days each, and thirteenth month with five or six days depending on the year. The year starts in September, around the 11th, and it is seven to eight years behind the Gregorian calendar. Our first patient was registered 22.04.00 in FRH. This day corresponds to January 1st 2008 in Norway. The registration date was not noted before the 3rd quarter in 2001 in the two health centers. Our last patients were registered from 21.04 to 02.05.03, which is from December 30th 2010 to

January 10th 2011 (23). The data collection was done in August 2011. Because of a treatment duration of six to eight months all of our included patients had time to finish their treatment and we were able to know their treatment outcome.

We chose to follow the Ethiopian Calendar in our data collection. All data were reported every quarter. We used the same quarters in our statistics. The quarters consisted of a time period of three months, with small variations of the exact length between the health facilities and from year to year. In our results, the two last quarters from one year were put together with the two first quarters from the next year to make up one year. In that way it became easier to compare the data with numbers from WHO and other countries using the Gregorian calendar. In the results, year 2000/2001 EC corresponds to our year 2008, 2001/2002 EC to 2009 and 2002/2003 EC to 2010.

3.5. Selection and recruitment of participants

We wanted to include as many TB patients as possible from Bahir Dar. With help from our contact person at the Regional Health Bureau in Bahir Dar we came in contact with FRH and the two largest public health centers in the city, Bahir Dar HC and Han HC. Our contact person helped with translating and explaining the aim of our project and the importance of looking into the old TB registration books. We clarified that we were not supposed to talk to the TB patients and that all the collected data would be anonymous with no names or addresses.

3.6 Inclusion criteria

All the patients registered in the TB registration books from 3rd quarter 2000 (EC) to the end of 2nd quarter 2003 (EC) in the three health facilities were included.

3.7 Exclusion criteria

These variables were excluded in our forms: name and address of the patient and his/her contact person, type of treatment and the duration of the continuation phase. Considering HIV co-infection, we did not focus on whether CPT or ART was started or if the patient was enrolled in HIV care or not.

3.8 Data collection, method

We collected the data from TB registration books, which were to be found in the TB office in the hospital and in the two health centers. We spent 3-7 days in each of these places, together three weeks. All the patient information was handwritten in tables and our job was to transfer this information anonymously into our almost identical self produced tables on our computer. The form we made for data collection was based on the form in the Ethiopian TB manual of 2008. The work was done without assistance. If any question turned up about the handwriting or the information in itself in the tables, we could ask the health workers in the TB clinic or our contact person from Regional Health Bureau. Also, we did observation in the three health facilities to collect relevant data besides the record review.

3.9 Data collection, variables

- Age
- Sex
- Smear result
- Weight
- Patient type/Patient category (e.g. *new*, *relapse*, *transfer in* etc.)
- Type of TB (ss+PTB, ss-PTB or EPTB)
- Start and length of the intensive phase
- HIV status
- Smear result and weight measurements in the continuation phase
- Treatment outcomes

Among the outcome-categories we added one more category named “*Missing*”, for all the patients with no outcome noted.

3.10 Data analysis, including definitions

Data analysis was performed using Microsoft Office Excel 2007 and manual counting and calculation. Proportions and percentages were computed, and we have used tables and graphs to present our results. The national TB control manual of 2008 (and annual reports from WHO) was used as a standard to compare results.

In our results we mention Types of cases and show the results of the different Treatment outcome. Here is the full list of definitions used (from the TB manual of 2008):

Definition of type of cases

A case of TB is a patient in whom tuberculosis has been confirmed bacteriologically or diagnosed by a clinician.

New case (N): A patient who never had treatment for TB, or has been on previous anti-TB treatment for less than four weeks.

Relapse (R): A patient declared cured or treatment completed of any form of TB in the past, but who reports back to the health service and is now found to be AFB smear-positive or culture positive.

Treatment Failure (F): A patient who, while on treatment, is smear-positive at the end of the fifth month or later, after commencing. Treatment failure also includes a patient who was initially sputum smear-negative but who becomes smear-positive during treatment.

Return after default (D): A patient previously recorded as defaulted from treatment and returns to the health facility with smear-positive sputum.

Transfer out (T): A patient who started treatment in one treatment unit and is transferred to another treatment unit to continue treatment (2).

Definitions of treatment outcome

Cured: An initially smear-positive patient who is sputum smear-negative at, or one „month“ prior to, the completion of treatment and on at least one previous occasion (usually at the end of the 2nd or 5th month).

Treatment completed: A patient who completed treatment but for whom smear results are not available at 7th month or one month prior to the completion of treatment.

Treatment failure: A patient who remains or becomes again smear-positive at the end of 5 “month” or later during treatment. Or a patient who was PTB-negative at the beginning and turned out smear-positive at the end of the intensive phase.

Died: A patient who dies for any reason during the course of treatment.

Defaulter: A patient who has been on treatment for at least 4 weeks and whose treatment was interrupted for 8 or more consecutive weeks.

Transfer out: A patient who started treatment and has been transferred to another reporting unit and for whom the treatment outcome is not known at the time of evaluation of treatment results.

“Missing” (not from the TB manual): A TB patient with no outcome noted.

Treatment success: The sum of patients who are declared “cured” and those who have “completed” treatment (2).

3.11 Ethics

Before we arrived in Ethiopia the Regional Health Bureau in Bahir Dar was consulted for permission to do our observational research and data collection. A description and the aim of our project were sent over. The patients names would not be used, only their sex and age. No conflicts were met.

4. RESULTS

4.1 Socio demographic information

This report includes a total number of 3,343 TB patients in the time period from 3rd quarter 2000 EC to the end of 2nd quarter 2003 EC (2008-2010). These patients are from three different health facilities in Bahir Dar in Ethiopia, Felege Hiwot Referral Hospital (FRH), Bahir Dar HC and Han HC.

FRH had 728, 733 and 574 TB patients in year 2000/2001 EC (2008), 2001/2002 EC (2009) and 2002/2003 EC (2010), respectively. Bahir Dar Health Center (HC) had 336, 263 and 201 TB patients in the same time period. The relatively new Han HC had 119, 163 and 226 TB patients. For notification, some data from Han HC are missing. The TB registration book with data from 1st – 3rd quarter 2001EC was not found. Totally, 559 (16.7%) were registered as ss+PTB patients, 1247 (37.3%) as ss-PTB patients and 1533 (45.9%) as EPTB patients. In all the three health facilities, most TB patients were between 15 and 34 years old; 59.2 % in Bahir Dar HC, 63.3% in Han HC and 57.5 % in FRH in 2010. The proportion of women varied from 48.3% to 52.9% in Bahir Dar and Han HC. In FRH it was 39.0% in 2010. A total male: female ratio among the TB patients for 2010 was 1.3:1.

Table 1: Overview of TB at the health facilities in Bahir Dar

	2000/2001 EC		2001/2002 EC		2002/2003 EC	
Bahir Dar HC						
Ss+PTB	104	(30.8%)	79	(30.0%)	64	(31.8%)
Ss-PTB	107	(31.7%)	65	(24.7%)	52	(25.9%)
EPTB	125	(37.0%)	119	(45.2%)	85	(42.3%)
Total	338**		263		201	
Women/men (% ♀)	167/171	(49.4%)	127/136	(48.3%)	101/100	(50.2%)
Total <15 years old	26	(7.7%)	28	(10.6%)	21	(10.4%)
Han HC *						
Ss+PTB	23	(19.3%)	27	(16.6%)	51	(22.6%)
Ss-PTB	44	(37.0%)	58	(35.6%)	72	(31.9%)
EPTB	52	(43.7%)	78	(47.9%)	103	(45.6%)
Total	119		163		226	
Women/men (% ♀)	63/56	(52.9%)	81/82	(49.7%)	111/115	(49.1%)
Total <15 years old	17	(14.2%)	22	(13.5%)	28	(12.3%)
FR hospital						
Ss+PTB	76	(10.4%)	72	(9.8%)	63	(11.0%)
Ss-PTB	335	(46.0%)	281	(38.3%)	233	(40.6%)
EPTB	315	(43.3%)	378	(51.6%)	278	(48.4%)
Total	728**		733**		574	
Women/men (% ♀)	301/427	(41.3%)	316/417	(43.3%)	224/350	(39.0%)
Total <15 years old	109	(15.0%)	166	(22.6%)	88	(15.3%)

*Data from 1st to 3rd quarter 2001 EC are missing.

** Include patients with unknown smear results.

4.2 Case notification

Figure 1-3 show the variation of case notification according to type of TB (ss+PTB, ss-PTB and EPTB) at the three health facilities during the time period 2000/2001 EC (2008) to 2002/2003 EC (2010).

Figure 1: Case notifications in Bahir Dar Health Center according to sputum smear result.

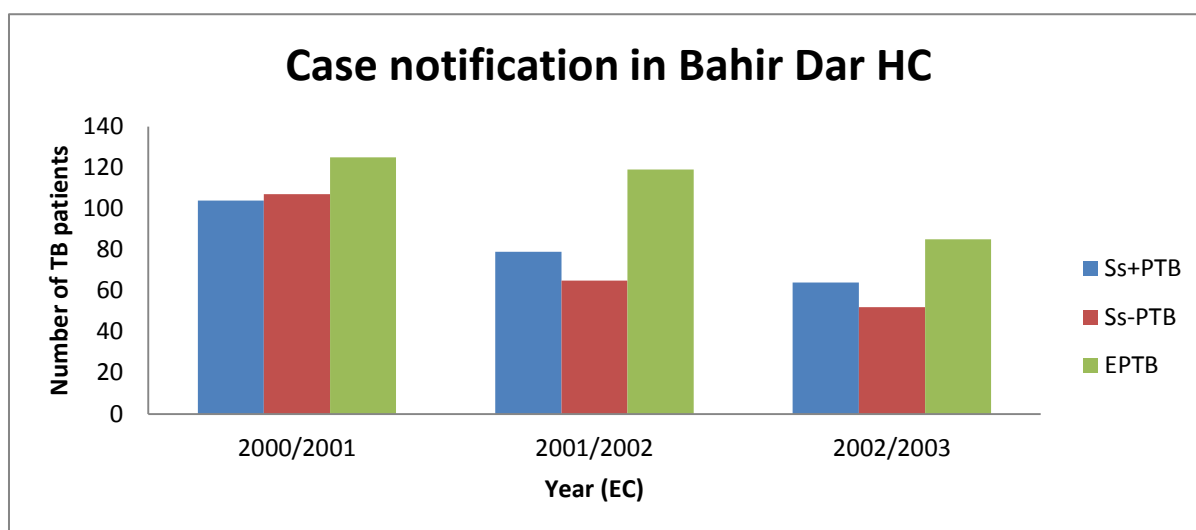


Figure 2: Case notifications in Han Health Center according to sputum smear result.

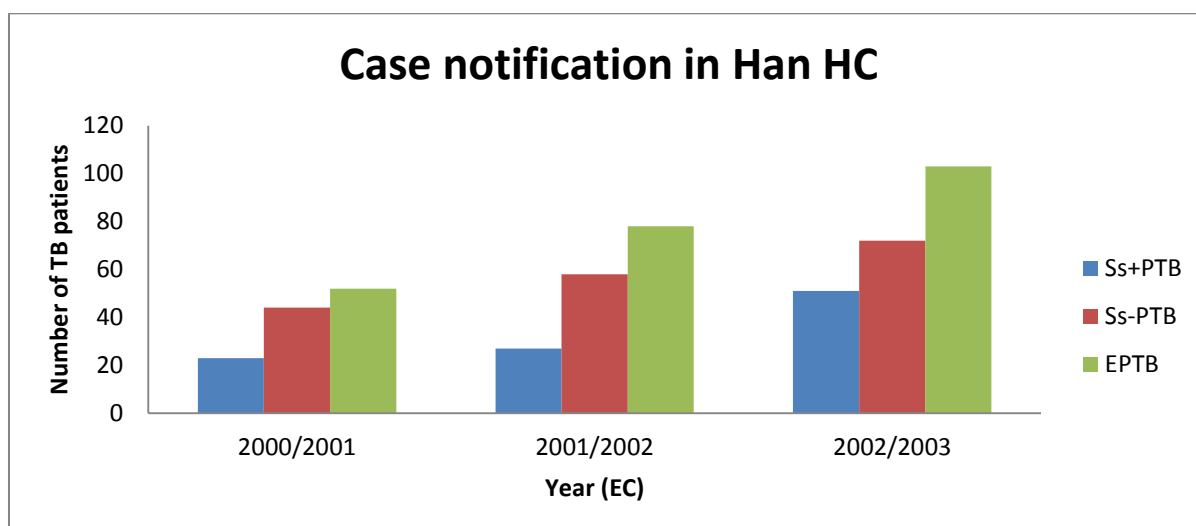
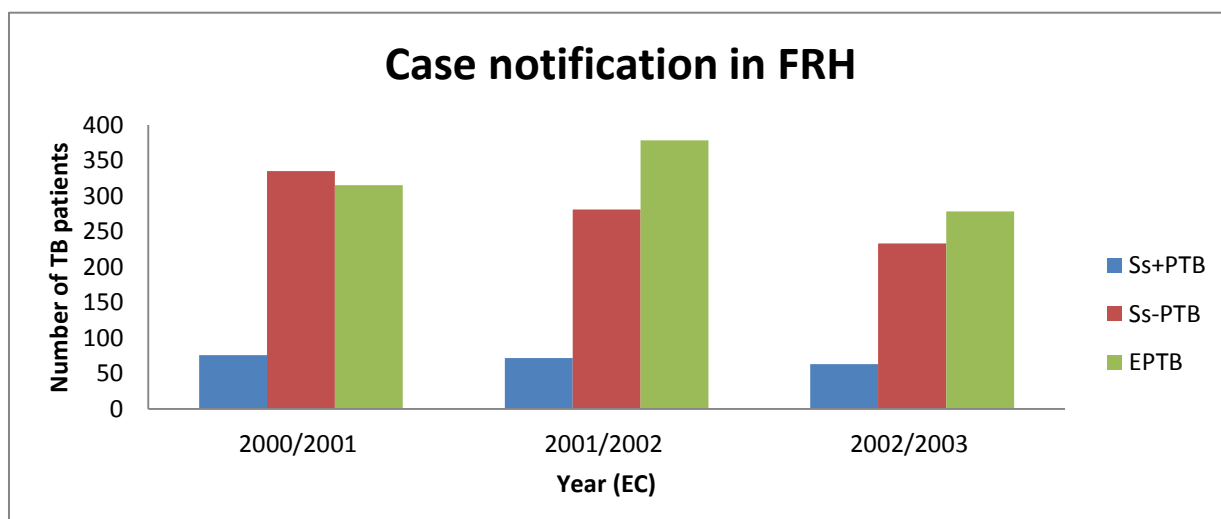


Figure 3: Case notifications in FRH according to sputum smear result.



Between 80.5% and 94.1% of the TB patients were registered as *new* patients (Table 2).

Table 2: Case notification according to type of patient category.

	2000/2001 EC		2001/2002 EC		2002/2003 EC	
Bahir Dar HC						
New	305	(90.2%)	226	(85.9%)	173	(86.1%)
Relapse	6	(1.8%)	7	(2.7%)	3	(1.5%)
Treatment after failure	1	(0.3%)	1	(0.4%)	0	(0%)
Treatment after default	1	(0.3%)	0	(0%)	2	(1.0%)
Transfer in patient	25	(7.4%)	28	(10.6%)	21	(10.4%)
Other	0	(0%)	1	(0.4%)	1	(0.5%)
Han HC						
New	112	(94.1%)	142	(87.1%)	182	(80.5%)
Relapse	1	(0.8%)	1	(0.6%)	9	(4.0%)
Treatment after failure	3	(2.5%)	0	(0%)	2	(0.9%)
Treatment after default	0	(0%)	0	(0%)	1	(0.4%)
Transfer in patient	3	(2.5%)	19	(11.7%)	24	(10.6%)
Other	0	(0%)	1	(0.6%)	6	(2.7%)
FRH						
New	619	(85.0%)	613	(83.7%)	498	(86.8%)
Relapse	6	(0.8%)	11	(1.5%)	17	(3.0%)
Treatment after failure	4	(0.5%)	1	(0.1%)	0	(0%)
Treatment after default	2	(0.3%)	0	(0%)	0	(0%)
Transfer in patient	96	(13.2%)	107	(14.6%)	59	(10.3%)
Other	1	(0.1%)	0	(0%)	0	(0%)

4.3 Age and gender distribution

The gender distribution (Figure 4 -6) was almost the same in all age groups at Bahir Dar HC and Han HC. One exception was the age group 35-44 years at Bahir Dar HC, which had almost twice as many men as women (21 vs. 11). At the hospital (FRH), there were overall more men than women. The biggest difference was in the age group 15-24 years with 81% more men than women (123 men, 68 women).

There were together 137 children (<15 years) in the three health facilities, constituting 13.7% of the total amount of TB patients in 2002/2003 EC (2010). In this age group there were 54.7% boys, and 45.3% girls. However, this varied a lot between the different health facilities.

Figure 4: Age and gender distribution at Bahir Dar HC 2002/2003 EC (2010).

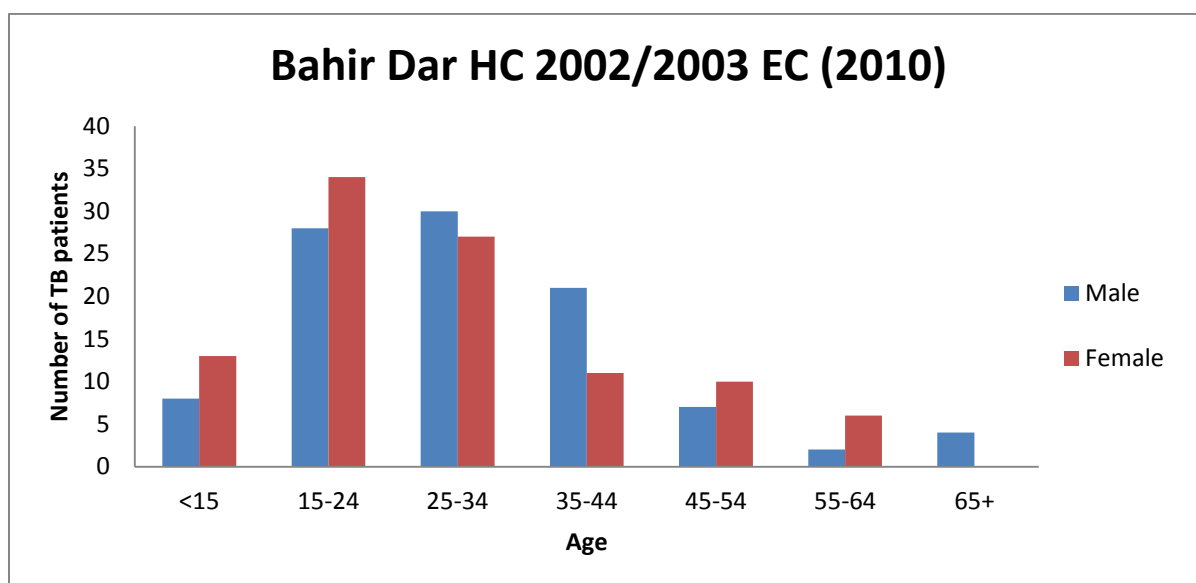


Figure 5: Age and gender distribution at Han HC 2002/2003 EC (2010).

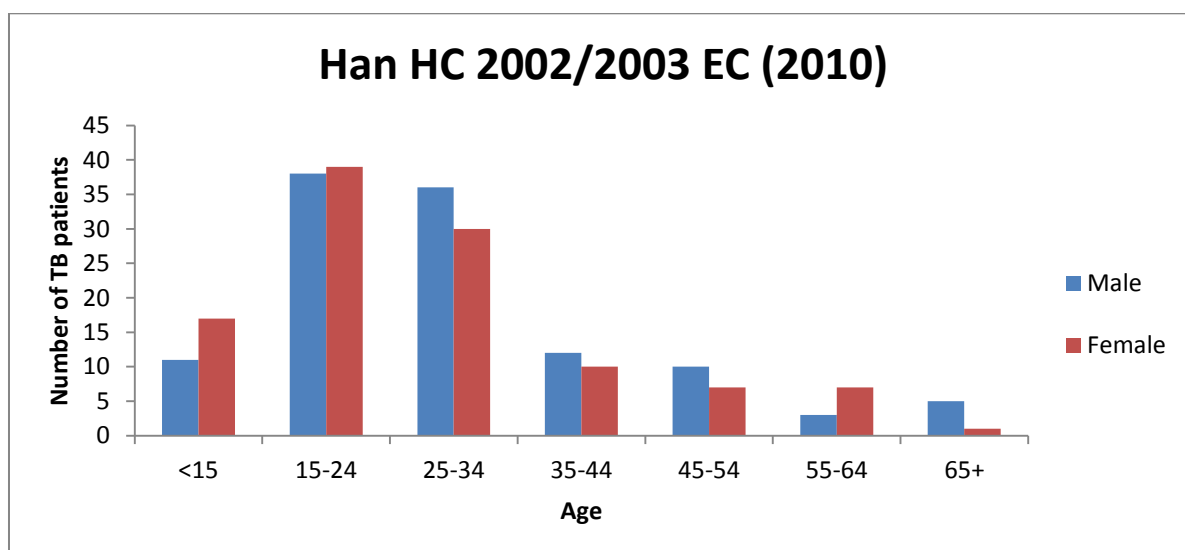
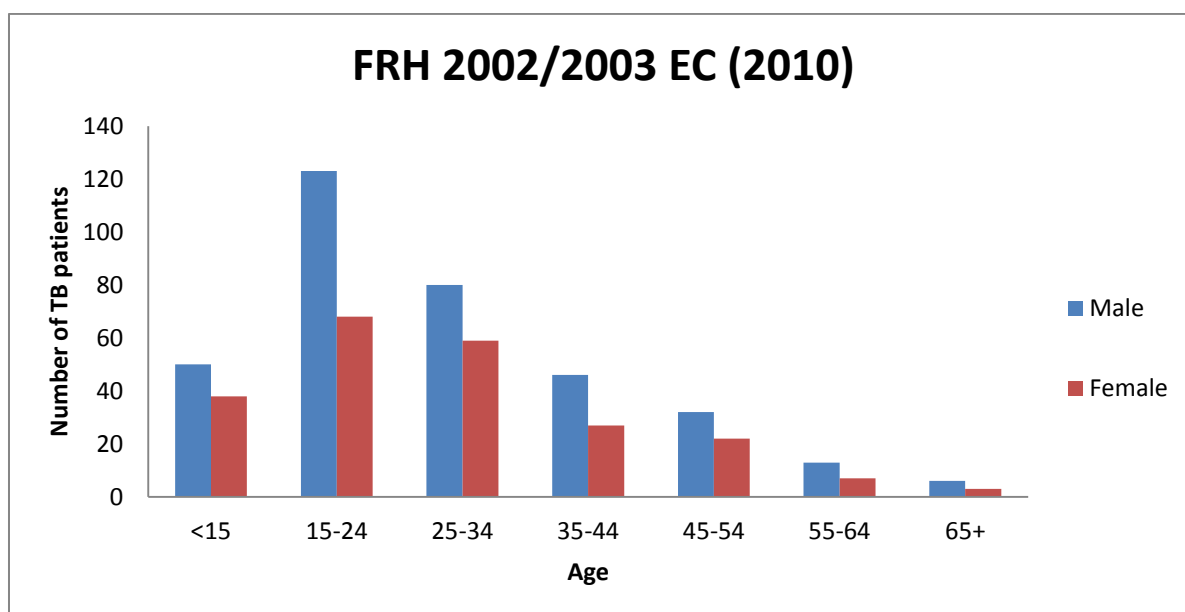


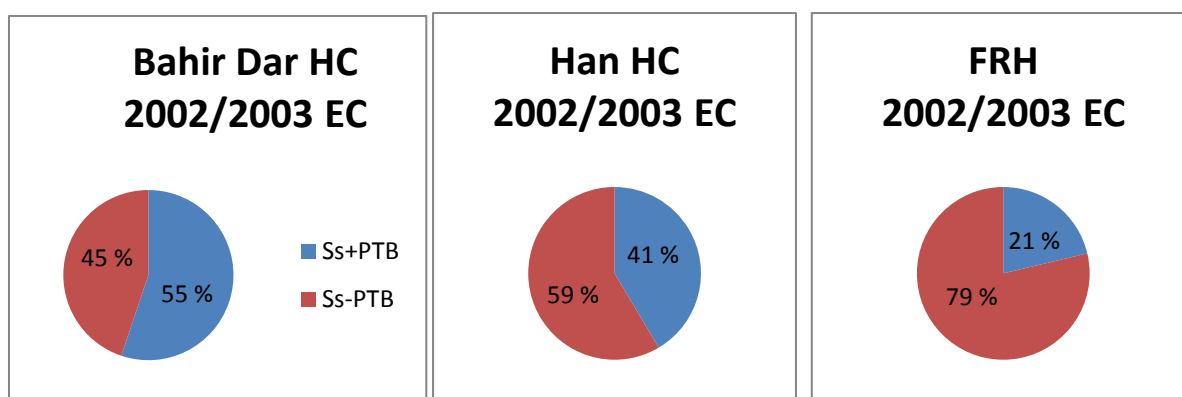
Figure 6: Age and gender distribution at FRH in 2002/2003 EC (2010).



4.4 Smear result

In 2002/2003 EC (2010), 58% of the patients at Bahir Dar HC, 54% at Han HC and 52% at FRH were classified as pulmonary TB patients. Out of these patients, 55%, 41% and 21%, respectively in those three health facilities had a positive sputum smear examination, hence notified in the category ss+PTB.

Figure 7 – 9: The proportion of Smear positive (Sm +) vs. Smear negative (Sm -) pulmonary TB patients in 2002/2003 EC (2010).



4.5 Conversion rate at 2 months

Table 3: Conversion rate after 2 months, from a smear positive to a smear negative sputum.

	2000/2001 EC	2001/2002 EC	2002/2003 EC
Bahir Dar HC			
Total no of ss+PTB patients	104	79	64
Tested after 2 nd month (no)	64	60	47
Conversion rate*	95.3%	86.7%	91.5%
No of wrongly not tested**	10	4	5
Han HC			
Total no of PTB+ patients	23	27	51
Tested after 2 nd month (no)	18	21	40
Conversion rate*	72.2%	90.5%	95.0%
No of wrongly not tested**	1	2	1
FRH			
Total no of PTB+ patients	76	72	63
Tested after 2 nd month (no)	32	35	30
Conversion rate*	93.8%	85.7%	96.7%
No of wrongly not tested**	8	9	4

* Only among the ss+PTB patients who had a sputum examination after 2nd month.

** No of TB patients who were wrongly not tested after 2nd month, which exclude transfer in/out patients and patients who died during the intensive phase.

After 2 months of treatment, ss+PTB patients are suppose to have a new sputum smear examination to see if there has been a conversion to a smear negative sputum. The conversation rate was more than 85% in all three places after 2000/2001 EC (2008), even up to 96.7 % in FRH in 2002/2003 EC (2010). These numbers only include those who actually had their sputum tested after two months. At Bahir Dar HC 28.8% in 2008, 19.0% in 2009 and 18.8% in 2010 were either transferred in after 2 months or transferred out or died before 2 months of treatment. In the same years, 9.6%, 5.1% and 7.8%, respectively had no reason reported for not having a new sputum examination after 2 months. At Han HC 4.3%, 7.4% and 2.0%, respectively were in the same latter category. At FRH 10.5%, 12.5% and 6.3% were wrongly not tested after 2nd month. The total proportion of TB patients who were wrongly not tested in 2010 was 5.6% (10 patients).

4.6 Treatment outcomes

Table 4: Treatment outcomes at the health facilities in Bahir Dar (excluding transfer out patients)

	Bahir Dar HC	Han HC	FRH	Total
2000/2001 EC (2008)				
Cured	38 (14.8%)	14 (14.3%)	23 (7.4%)	75 (11.3%)
Completed	186 (72.7%)	59 (60.8%)	157 (50.8%)	402 (60.7%)
Died	4 (1.6%)	2 (2.1%)	29 (9.4%)	35 (5.3%)
Failure	0 (0.0%)	1 (1.0%)	0 (0.0%)	1 (0.2%)
Default	6 (2.3%)	7 (7.2%)	19 (6.1%)	32 (4.8%)
Missing	21 (8.2%)	14 (14.4%)	81 (26.2%)	116 (17.5%)
DIC	1 (0.4%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
Total	256 (100%)	97 (99.8%)	309 (99.9%)	662 (100%)
2001/2002 EC (2009)				
Cured	42 (18.6%)	15 (10.4%)	34 (10.0%)	91 (12.8%)
Completed	148 (65.5%)	116 (80.6%)	180 (52.8%)	444 (62.4%)
Died	9 (4.0%)	2 (1.4%)	15 (4.4%)	26 (3.7%)
Failure	2 (0.9%)	1 (0.7%)	1 (0.3%)	4 (0.5%)
Default	12 (5.3%)	5 (3.5%)	4 (1.2%)	21 (3.0%)
Missing	12 (5.3%)	5 (3.5%)	107 (31.4%)	124 (17.4%)
DIC	1 (0.4%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
Total	226 (100%)	144 (100.1%)	341 (100.1%)	711 (99.9%)
2002/2003 EC (2010)				
Cured	36 (20.9%)	30 (16.1%)	26 (10.0%)	92 (14.9%)
Completed	102 (59.3%)	137 (73.7%)	131 (50.4%)	370 (59.9%)
Died	9 (5.2%)	8 (4.3%)	26 (10.0%)	43 (7.0%)
Failure	3 (1.7%)	2 (1.1%)	0 (0.0%)	5 (0.8%)
Default	20 (11.6%)	8 (4.3%)	1 (0.4%)	29 (4.7%)
Missing	1 (0.6%)	1 (0.5%)	72 (27.7%)	74 (12.0%)
DIC	1 (0.6%)	0 (0.0%)	4 (1.5%)	5 (0.8%)
Total	172 (99.9%)	186 (100%)	260 (100%)	618 (100.1%)
All years, 2008-2010				
Cured	116 (17.7%)	59 (13.8%)	83 (9.1%)	258 (13.0%)
Completed	436 (66.7%)	312 (73.1%)	468 (51.4%)	1216 (61.1%)
Died	22 (3.3%)	12 (2.8)	70 (7.7%)	104 (5.2%)
Failure	5 (0.8%)	4 (0.9%)	1 (0.1%)	10 (0.5%)
Default	38 (5.8%)	20 (4.7%)	24 (2.6%)	82 (4.1%)
Missing	34 (5.2%)	20 (4.7%)	260 (28.6%)	314 (15.8%)
DIC	3 (0.5%)	0 (0.0%)	4 (0.4%)	7 (0.4%)
Total	654 (100%)	427 (100%)	910 (99.9%)	1991 (100.1%)

A high number of the total amount of TB patients was transferred out, e.g. 14.4%, 17.7% and 54.6% in 2010 at Bahir Dar HC, Han HC and FRH, respectively. These “transfer-out” patients are excluded in Table 4 and in the following part.

“DIC” is something the health workers used to write when the patients had to discontinue their treatment because of serious side effects (jaundice etc.) Bahir Dar HC had 3 TB patients in this category from 2008 – 2010, Han HC had 0 patients and FRH had 4 patients.

Bahir Dar HC had a total success rate (cured + completed) for all the three types TB patients of 87.5% in 2000/2001 EC (2008), 84.1% in 2001/2002 EC (2009) and 80.2% in 2002/2003 EC (2010). 4 patients (1.6%) died in 2008. 3 (75%) of these patients were HIV positive. 2009 had 9 deaths (4.0%), 4 (44.4%) were HIV positive. 2010 had 9 deaths (5.2%), 8 (88.9%) were HIV positive. 11.6% of the TB patients in 2010 were noted as *defaulters*, hence did not complete their treatment.

At Han HC, 75.3% of those who started TB treatment in 2000/2001 EC (2008) completed with success, 91.0% in 2001/2002 EC (2009) and 89.8% in 2002/2003 EC (2010). 2 (2.1%) TB patients died in 2008, 2 (1.4%) in 2009 and 8 (4.3%) in 2010. Out of these, 1 (50%), and 6 (75%) were HIV positive in 2009 and 2010, respectively. There was no recording of HIV status in 2008. Han HC had 8 (4.3%) TB patients noted as defaulters in 2010.

At FRH, 58.3% completed their TB treatment with success in 2000/2001 EC (2008), 62.8% in 2001/2002 EC (2009) and 60.4% in 2002/2003 EC (2010). The number of patients who died in 2008 was 29 (9.4%), of which 17 (58.6%) were HIV positive. 2009 had 15 deaths (4.4%), 9 (60.0%) were HIV positive. 2010 had 26 deaths (10.0%), 18 (69.2%) were HIV positive. 1 (0.4%) TB patient was noted as defaulter in 2010.

Patients categorized as “missing” are those who were not put into an “outcome-category”; the health workers had not written any outcome for that patient. At Bahir Dar HC 21 patients (8.2%) had an unknown outcome in 2008, 12 patients (5.3%) in 2009 and 1 patient (0.6%) in 2010. At Han HC 14 patients (14.4%) in 2008, 5 patients (3.1%) in 2009 and 1 patient (0.5%) in 2010 had an unknown outcome. In the same category FRH had 81 patients (26.2%) in 2008, 107 patients (31.4%) in 2009 and 72 patients (27.7%) in 2010.

Out of all the TB patients in all the three health facilities 10 patients were noted as *failure*; 0.5%. 5 of these patients were treated in Bahir Dar HC.

4.7 Success rate for each category

Table 5 shows the cure rate for ss+PTB patients and the treatment success (cured + completed) rate for ss+PTB patients and ss-PTB/EPTB patients. We have only included those patients who completed the treatment in that health facility. This means that “transfer out” patients were excluded.

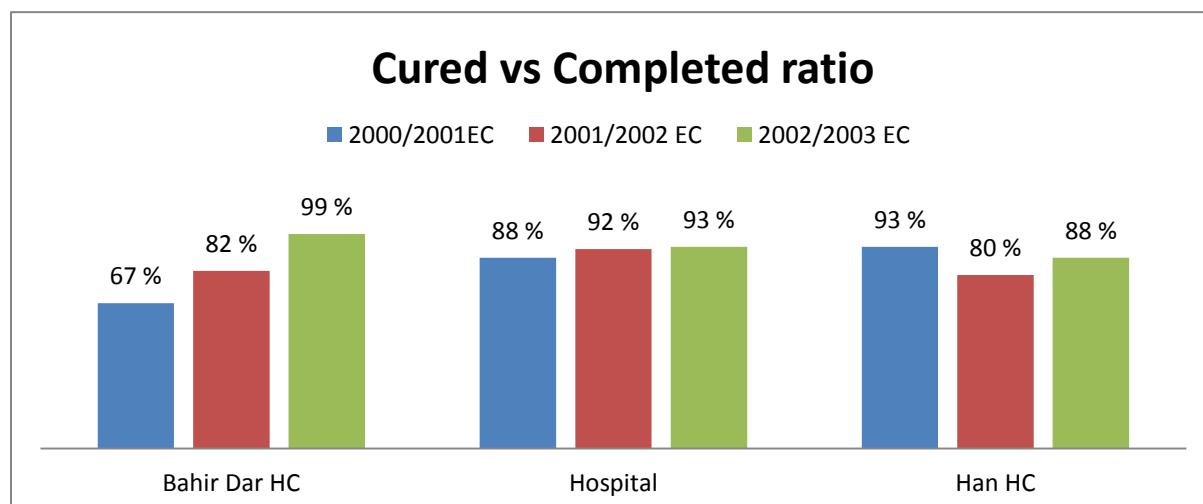
Table 5: Cure rate (CR) and Treatment success rate (TSR) for each category*

	2000/2001 EC	2001/2002 EC	2002/2003 EC
Bahir Dar HC			
Ss+PTB, CR	38/68 (55.9%)	42/66 (63.6%)	36/51 (70.6%)
Ss+PTB, TSR	57/68 (83.8%)	50/66 (75.8%)	37/51 (72.5%)
Ss-PTB/EPTB, TSR	166/187 (88.8%)	139/159 (87.4%)	101/121 (83.5%)
Han HC			
Ss+PTB, CR	14/18 (77.8%)	15/23 (65.2%)	30/41 (73.2%)
Ss+PTB, TSR	15/18 (83.3%)	20/23 (87.0%)	34/41 (82.9%)
Ss-PTB/EPTB, TSR	58/79 (73.4%)	111/121 (91.7%)	133/145 (91.7%)
FRH			
Ss+PTB, CR	23/42 (54.8%)	34/44 (77.3%)	26/37 (70.3%)
Ss+PTB, TSR	26/42 (61.9%)	37/44 (84.1%)	28/37 (75.7%)
Ss-PTB/EPTB, TSR	154/258 (59.7%)	177/296 (59.8%)	129/224 (57.6%)

* “Transfer out” patients are excluded

4.8 Outcome of ss+PTB patients: Comparison of cured vs. completed at the different health facilities

Figure 13: Treatment outcomes among ss+PTB patients; cured versus completed.



Among ss+PTB patients who were treated with success, more than 80% were notified as cured. The exception was Bahir Dar HC in 2000/2001 EC (2008). Note: These ratios should be seen in the context of the success rates in table 5.

4.9 HIV prevalence among the TB patients

The patients' HIV status was registered from 2001 EC in the two health centers, in the hospital from 3rd quarter 2000 EC, or even earlier.

Table 6: TB/HIV

	2000/2001 EC	2001/2002 EC	2002/2003 EC
Bahir Dar HC			
TB patients with known HIV status	-	177 (67.3%)	150 (74.6%)
HIV- positive TB patients	-	99 (55.9%)	70 (46.7%)
Han HC			
TB patients with known HIV status	-	155 (95.1%)	216 (95.6%)
HIV- positive TB patients	-	57 (36.8%)	54 (25.0%)
FRH			
TB patients with known HIV status	366 (50.3%)	473 (64.5%)	450 (78.4%)
HIV- positive TB patients	253 (69.1%)	186 (39.3%)	159 (35.3%)

In 2002/2003 EC (2010), Bahir Dar HC had 201 TB patients. 150 (74.6 %) of these patients had a known HIV status, either tested at their first visit at the TB clinic or earlier. Out of these tested TB patients, 70 patients (46.7%) were HIV positive. In 2001/2002 EC (2009) 67.3% had a known HIV status, and 55.9% of these were HIV positive.

At Han HC 95.1% and 95.6% were tested or had a known HIV status in 2009 and 2010, respectively. Out of these patients 36.8% and 25.0% were HIV positive.

At FRH 50.3% were tested for HIV in 2000/2001 EC (2008), 64.5% in 2001/2002 EC (2009) and 78.4% in 2002/2003 EC (2010). Out of these patients 69.1%, 39.3% and 35.3% had a positive test.

The total HIV prevalence for all the three health facilities was in 2010 of 34.7%, with a total test rate of 81.5%.

Figure 14-15: TB/HIV every quarter from 1st quarter 2001 EC to end of 2nd quarter 2003 EC.

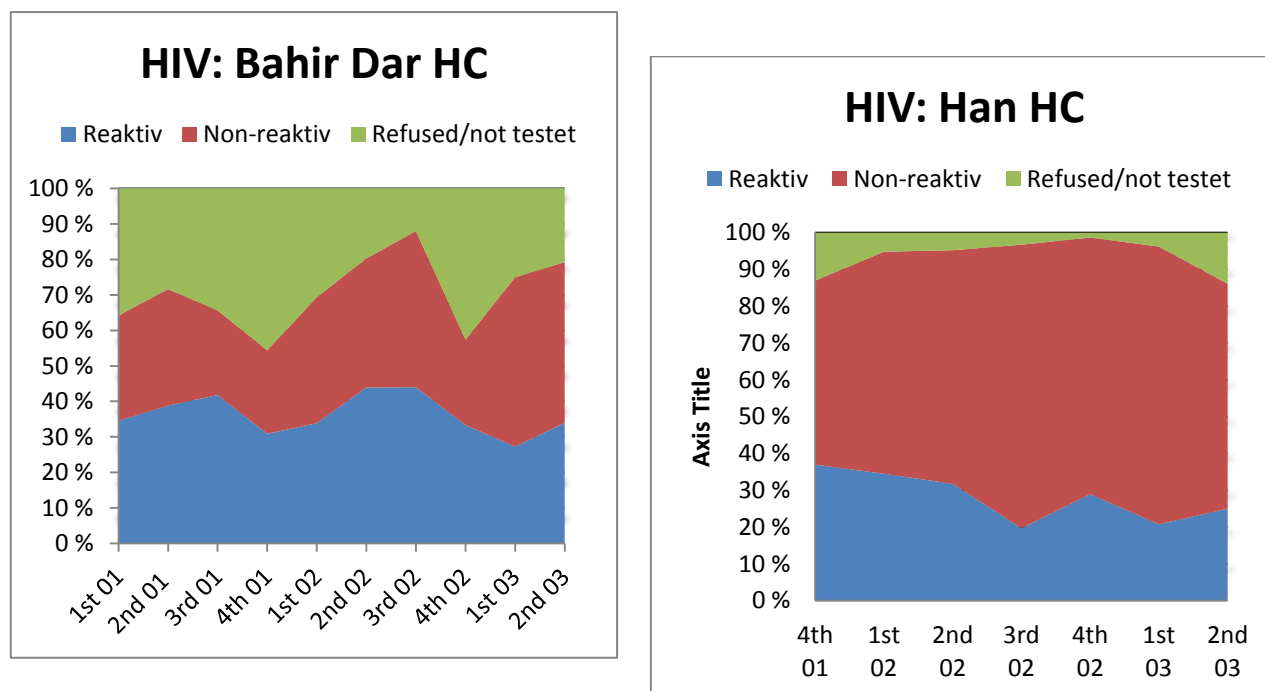
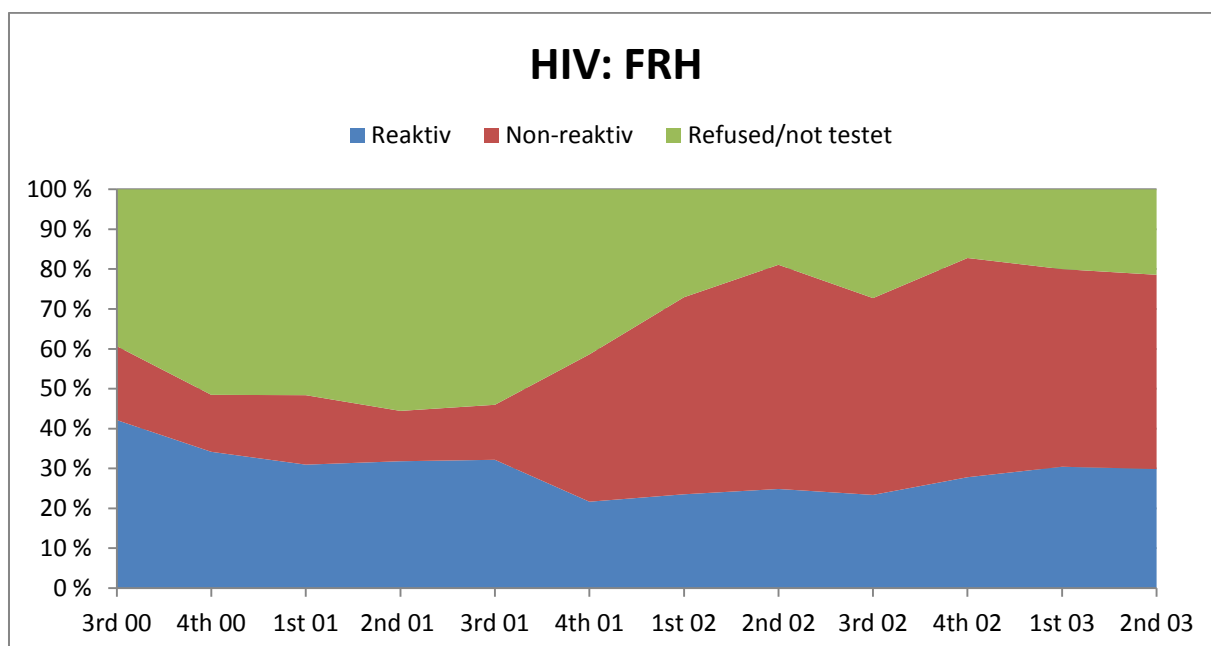


Figure 16: TB/HIV every quarter from 3rd quarter 2000 EC to end of 2nd quarter 2003 EC (2008 – 2010).



4.10 Weight Recording

Table 7: Weight recording in TB patients (%)

	2000/2001 EC	2001/2002 EC	2002/2003 EC
Bahir Dar HC			
Weight recorded at 1 st visit (%)	91,1	92,0	97,0
Weight recorded after 1 st visit (%)	27,5	28,9	5,7
Han HC			
Weight recorded 1 st visit (%)	92,4	98,8	99,6
Weight recorded after 1 st visit (%)	0,0	11,1	53,5
FRH (hospital)			
Weight recorded 1 st visit (%)	92,2	97,4	99,5
Weight recorded after 1 st visit (%)	29,6	19,8	29,4

At Bahir Dar HC in year 2002/2003 EC (2010), 97% of the TB patients had their weight measured and noted at their 1st visit or in the beginning of their treatment. 5.7% of the patients had their weight noted a second time after the two months of the intensive phase of the treatment period.

At Han HC and FRH 99.9 % and 99.5 %, respectively, of the TB patients had their weight noted at their 1st visit in 2010. 53.5 % and 29.4 % had their weight noted a second time. To see the numbers for the two previous years, see Table 7.



Picture 1: Manually weight measurement in FRH.

4.11 Observations

Here are some of the observations we made in the three health facilities in Bahir Dar town:

- The new six months treatment regime (2RHZE/4RH) with four months of RH in the continuation phase was only offered children (<15). All the other patients recieved the old eight months regime (2RHZE/6EH) with six months of EH.
- The use of fixed dose combination of drugs was well implemented.
- CXR was only available at the hospital.
- Observations from the TB registration books:
 - The duration of the intensive phase of the treatment regime varied between the patients, i.e. not always 28 x 2 days were marked in the registration books. The same applied for the continuation phase.
 - At FRH, more than 50% of the TB patients were transferred out. For most of these patients, the name of the new treatment unit was registered. Unfortunately, there was no good feedback system. Did they actually turn up at their new place?

5. DISCUSSION

5.1 General

The total number of TB cases at the three largest public health facilities in the Ethiopian town Bahir Dar, has shown a declining trend during the three years from 2008 to 2010. Together, FRH, Bahir Dar HC and Han HC had 1,185 TB cases in 2008, 1,159 in 2009 and 1,001 in 2010. The numbers of *new* cases were 1,036, 981 and 853 for the same years. The real difference is probably higher due to missing data at Han HC (two quarters in 2008 and one quarter in 2009). It is also worth noting that Han HC is a newly established HC, and it might take some time before the proper patient load is built up and all the routines are implemented. Because of this, it is hard to say if the real TB burden at Han HC has increased or if it has been relatively stable from 2008 to 2010. The reduction of the total number of TB cases, was higher in Bahir Dar HC (43%) compared to the hospital (20%) during this time period.

Ethiopia, including Bahir Dar has a growing private health sector (24). The DOTS coverage of the private clinics is also increasing, but it is still less than in the public health facilities. We have no exact data for the DOTS coverage of the private health centers in Bahir Dar. A decrease in the number of new TB cases would have been consistent with the global WHO report from 2011 saying that the absolute number of TB cases has been falling since 2006, and the incidence from 2002 (1). Since more people seek help in the private clinics (24) and not all of these clinics have an obligatory reporting system (in our study period), it is hard to determine if the total TB burden in Bahir Dar is falling or not.

5.2 Age and gender distribution

Both globally and nationally, TB mostly affects young adults and men more than women (1;25). We generally found this to be true in Bahir Dar as well, although the male proportion of TB patients may not be as high as in most national statistics. In 2000/2003 EC (2010), our numbers show that 84.4% of the TB patients in Bahir Dar were 15-64 years of age. Most of these were between 15-34 years (59.2% in Bahir Dar HC, 63.3% in Han HC, and 57.5% in FRH). It is estimated that a TB patient on average loses 20-30% of their annual income (26). Hence it is a big socio economic problem that TB mostly affects people in their most productive years (2).

The amount of TB patients less than 15 years was 13.7% (10.4% in Bahir Dar HC, 12.3% in Han HC and 15.3% in FRH). Only a few patients were above 65 years. It is not until recently that WHO has requested countries to make their TB notification age and gender disaggregated for more than the ss+PTB patients. Therefore, it is hard to compare our numbers to the global statistics from 2010. If we look at the numbers for 2011, they show that most patients (88%), are in the age group 15-64, and only 6% are less than 15 years old (1). Hence, the percentage of pediatric TB patients recorded in Bahir Dar was higher than the global average, which may be explained by the high proportion of children in the country. However, the amount of TB cases less than 15 years is still low to which there might be several contributing factors; many children are treated in pediatric wards, which often show a lower TB notification. The TB disease is also harder to detect and diagnose in children and the proportion of EPTB is higher. The public priority might also be lower (27).

As stated earlier, there are globally more male than female TB patients. It was estimated that women accounted for 36% of the incident cases globally in 2010 (25). The numbers from Bahir Dar show a higher female proportion; 50.2% at Bahir Dar HC, 49.1% at Han HC and 39.0% at FRH. This gives a total male: female ratio of 1.3. This ratio seemed to correspond to the national ratio calculated for 2011, which was 1.2. The global ratio of 1.7 (varying from 1.1 to 2.2 in the different WHO regions) states more men (1). Hence, it may seem like the gender difference is less prominent in Bahir Dar; men and women totally account for about 50:50 of the TB patients. Bahir Dar is known to be a hot spot for HIV(22), and since the prevalence generally is higher among women (26), this might make the female inhabitants more prone to TB and explain the high female proportion of the TB patients.

However, the hospital had overall more male TB patients. The biggest difference was seen in the age group 25-34 years, where there are 80% more men. The reason for the high male proportion is poorly understood, but one contributing factor might be different health seeking behavior between the genders. Another reason may be a difference in the risk of exposure. Men more often work outside the house and might be surrounded by contagious TB patients. Women on the other hand, tend to stay at home and are not so prone to be infected. Lower detection of female TB cases might also contribute. Women less often present with the classical symptoms of cough and sputum production, and standard microscopy screening less often reveal positive sputum smear (26).

5.3 Smear result

According to the 2008 TB manual, normally and in a global perspective, 85% of all TB cases are PTB cases. EPTB cases compromise 12-14%. In Ethiopia, only 66% of the TB cases were reported as PTB cases in 2010, while 33% were reported as ETPB cases (25). All the health facilities in Bahir Dar had a proportion of PTB patients of less than 60% in 2010.

The TB manual further states that among the PTB cases 75-80% are ss+PTB cases. In Ethiopia the ss+PTB vs. ss-PTB ratio is closer to 50:50; with 47% registered as ss+PTB in 2010. In Bahir Dar, the two health centers more or less followed this 50:50 distribution, but FRH had a much higher proportion of ss-PTB; 79%. Only 11% of *all* the TB patients at the hospital were noted as ss+PTB in 2010.

Microscopic examination of sputum is the primary tool for diagnosing TB. It is rapid, simple and economic favorable, and has a high specificity. However, the sensitivity is variable (40-60%) (1). The Ethiopian national survey conducted in 2011 identified 43% of the TB cases by microscope. The remaining 57% were sputum smear negative and culture positive (21).

Culture diagnosis was rarely used in the three health facilities in Bahir Dar, but this survey emphasizes the need of significantly expanding the culture diagnostic services.

According to the 2008 TB manual the ss-PTB diagnosis should be based on clinic, no response to a course of broad-spectrum antibiotics, three negative sputum smear examinations with direct microscopy *and* radiological abnormalities consistent with PTB (2). There were no X-ray-facilities in the two public health centers, only in the hospital. This means that the patients in the health centers had to get a CXR at the hospital or in private clinics. In terms of x-ray, the 2011 survey also found that among all confirmed TB cases, 50% did not have chronic cough and were identified only by CXR screening (21). This shows the importance of CXR in the case detection work. On the other hand, CXR is less specific and 40% diagnosed as TB patients by x-ray alone may not have active TB (2).

One explanation for the low proportion of ss+PTB patients noted in the health facilities in Bahir Dar may be the diagnostic facilities and the expertise in the different places. Lack of trained lab workers and old and poorly functioning microscopes are contributing factors. In terms of the very low proportion of ss+PTB patients at FRH, there is a possibility that more ss-PTB patients were referred to the hospital in the first place, possibly because of unclear chest infection. There is also a possibility of over diagnosis. Patients can have been put on anti-TB treatment without smear result, based on quicker and less specific methods like clinic

and CXR findings. This will give a false high number of ss-PTB patients, which can have been incorrectly treated. This again can have contributed to the poor treatment outcome observed at the hospital.

Another possible reason for the high proportion of ss+PTB patients could be the generally high HIV prevalence. The proportion of ss-PTB patients is often much higher among HIV positive TB patients than among HIV negative patients. HIV-infected ss+PTB patients have a tendency to excrete significantly less bacilli in their sputum, and in the advanced stages of HIV infection, many develop ss-PTB (2).

It is hard to explain the high proportion of EPTB patients (>30%) seen in Bahir Dar and in Ethiopia in general. In 2011, this proportion was 14.5% globally, and 18% in the African Region. Further studies could be conducted to explain these differences.

5.4 Conversion rate after 2 months of treatment

The conversion rate from a positive sputum smear to a negative sputum smear in the ss+PTB patients was more than 90% in all the three health facilities in 2002/2003 EC (2010). An improvement from 2008 was especially seen in Han HC, which had a conversion rate of only 72.2% in 2008. This calculation is only done for those ss+PTB patients who had a 2nd sputum examination. Of all the ss+PTB patients, only a certain number of patients were followed up in the same health facility with a new sputum examination after 2 months. In FRH this part was less than 50% in all the three years. However, the majority of the patients who were not tested a 2nd time had a “valid” reason, e.g. they were transferred in after or transferred out before 2nd month, or died before 2 months of treatment. The problem is the patients who were *wrongly not tested* after 2 months. FRH generally had the highest number of these patients, which also reflects the high number of TB patients with missing outcome at FRH (see later).

According to the TB manual all ss+PTB patients on TB treatment must have one sputum specimen examined at the end of the 2nd, 5th and 7th month. The results should be noted in the Unit TB Register in the TB registration books. If a new sputum examination is not done at the end of the 2nd month, there is a risk of ignoring a patient who is still contagious and also possibly drug resistant, and who needs to continue the intensive phase treatment for an additional 4 weeks. Normally the load of bacilli in the sputum is rapidly reduced, usually within 2-3 weeks (1). A still positive sputum result after 2 months of treatment can be due to

bad compliance/not daily drug collection, or drug resistance. This is why it is so important to discover these patients (2). In terms of a poor feedback system between the health facilities, we also question how many of the transfer out patients really turned up in the new health facility and received a new sputum examination.

5.5 Cured vs. completed (ss+PTB patients)

One of the targets of DOTS and the Stop TB Strategy is to ensure cure of all the TB patients. To be classified as *Cured* according to the TB manual, the patient is initially sputum smear positive, and then is sputum smear negative at, or one month prior to the completion of the treatment and on at least one previous occasion. If the last smear result was not available or done, but drugs for all the 6 or 8 months have been collected, the patient is declared *Treatment completed*. The ratio of cured vs. completed among ss+PTB cases were mostly good for all the three health facilities in Bahir Dar, with a cured vs. completed ratio above 80% after 2008. Bahir Dar HC had the best result for 2010 with a ratio of 99%, which had gradually improved from 2008 (only 67%). This can indicate that a higher proportion was followed up with smear examinations. The ratios from FRH have been more stable, but improving from 88% in 2008 to 93% in 2010. In Han HC the ratios varied between 80% and 92%. It is important to see these ratios in comparison to the overall treatment success rates (treatment + completed) among the ss+PTB patients. At Bahir Dar HC, the treatment success rate was only 72.5% in 2010.

5.6 Treatment outcomes and treatment success rates

FRH had the lowest treatment success rate among the three health facilities in Bahir Dar, with an overall success rate of only 60.4% in 2002/2003 EC (2010). As an indicator of the quality of TB care, treatment success rate is very important. The global target for 2015 is a success rate of 90% (14), and FRH has a long way to go before reaching that. Both Bahir Dar HC and Han HC had higher success rates among ss-PTB/EPTB patients compared to ss+PTB patients. FRH had the opposite. Han HC had the best success rates, both overall and for each of the TB types, but the target of 90% was only accomplished for ss-PTB/EPTB cases. To compare with Ethiopia in general, ss-PTB/EPTB patients had a success rate of 75% in 2010 (1), declining from 80% in 2009 (25). In FRH the treatment success rate for this category was only 57.6% in 2010, in Bahir Dar HC 83.5%. Among the more infectious ss+PTB patients the success rate

was 83% for Ethiopia in general in 2010 (1). Again, only Han HC could match this, with a success rate of 82.9%.

As could be expected due to more severe cases seen in hospitals, FRH had generally higher mortality rates compared to the two health centers (10% in 2010). But a decline in the mortality rate was not seen in any of the three health facilities from 2008 to 2010, rather a slightly increase. Generally, more than 50% of the TB patients who died during their treatment were co-infected with HIV. A limitation of this number is that the data does not say anything about the real cause of death or how sick the patients were due to HIV and/or TB at the time of diagnosis. Evidence show that if HIV is early diagnosed and patients are put on anti-TB and anti-retroviral treatment, the response is very good. HIV co-infected TB patients usually die if TB is diagnosed at the late stage of HIV (2;28). When it comes to delay, a study has showed that diagnostic delay is a serious challenge in Ethiopia. The major proportion of the total delay was related to health providers (29). In late stages of HIV-infection TB infection is more likely to present with an atypical pulmonary disease and the proportion of ss-PTB cases is higher (2). This can contribute to an even longer diagnostic delay in this patient category.

The mortality rate in the African Region is falling, but not fast enough to reach the target of Stop TB Partnership of halving the death rate by 2015 compared to 1990 levels (1). The two WHO TB profiles for Ethiopia from 2010 and 2011 differ a lot in terms of showing mortality rates from 1990. But according to the latest profile from 2011 Ethiopia is on track of reaching the global target.

TB patients with no outcome reported were a big problem, especially in FRH where 27.7% fell into this category in 2010. We categorized them as “*missing*”. Our data does not say anything about the reason for no outcome. But because the noted number of “*defaulters*”¹ in FRH only were 0.4%, it is reasonable to assume that most of these “*missings*” should have been noted as defaulters. It is also a possibility of unregistered *transfer outs*, unreported deaths and a higher real mortality rate. The two health centers had less TB patients in the “*missing*”-category, and only one each in 2010. However, Bahir Dar HC had 11.6% notified as defaulters in 2010. Both defaulters and patients with no noted outcome are problems in terms of incomplete treatment, higher risk of relapse, and a contributing factor to the spread of

¹ A patient who has been on treatment for at least 4 weeks and whose treatment was interrupted for 8 or more consecutive weeks

TB infection and development of MDR-TB (1). To improve treatment success rate it is important to make sure that all TB patients complete the treatment. Han HC had a low number of defaulters and “missings”, thus higher success rates.

5.7 TB/HIV

Generally in Ethiopia, only 43 % of the TB patients had a known HIV status in 2002/2003 EC (2010) (25). In Bahir Dar we found much higher test rates. In 2010, 75% of the TB patients in Bahir Dar HC were tested for HIV, in FRH 78% and in Han HC as many as nearly 96%.

While Han HC had high test rates in both 2009 and 2010 (no data from 2008), FRH had a large improvement over a half year period from only 46 % after 3rd quarter 2001 EC, to a test rate of 73 % after 1st quarter 2002 EC. Bahir Dar HC also improved, but less, from 67 % in 2009 to 75 % in 2010. In comparison, HIV testing among TB patients reached 59 % in the African Region and 34 % globally in 2010 (25). According to the 2008 TB manual, and as a part of the TB-HIV collaboration work, all TB patients should be offered a HIV test (2). Both HIV testing for TB patients and antiretroviral therapy (ART) were available and free in all the three health facilities. Economical consequences should therefore not be any reason for the TB patients to refuse HIV testing. However, TB and HIV are associated with stigma (2), which could be an important factor. There is also a possibility that some patients, especially in FRH and Bahir Dar HC, never were offered the HIV test. This can be due to lack of capacity, equipment or awareness of the importance of HIV testing.

The HIV prevalence among the *tested* TB patients was also higher in FRH (35%), Bahir Dar HC (47%) and Han HC (25%) than the prevalence of 15% generally in Ethiopia in 2010. The HIV prevalence declined in all the three health facilities from 2008 to 2010, despite a big increase in the number of patients tested. Globally in 2010, 23% of TB patients with an HIV test result were HIV positive, and in the African Region as much as 44 % (25). In 2011 the estimated HIV prevalence in the Ethiopian population was 1.5% (25), declined from 2.3% in 2009 (18). The prevalence is higher in urban areas (4.2% in 2011, rural 0.6%). There are also geographical variations. In 2008 the estimated HIV prevalence in urban settings in Amhara Region was 10.7%, compared to 7.7% in urban settings generally in Ethiopia (18).

Bahir Dar is one of the hot spot areas for HIV with an estimated HIV prevalence of 13.8% in 2005 (22). This might be due to lack of information or knowledge, poverty in the population, cultural influence and sexual behavior. The high HIV prevalence in Bahir Dar can have

contributed to the high HIV prevalence found among the TB patients in our study compared to the national prevalence. We do not have any information about whether the HIV prevalence generally is higher in the public health facilities compared to the private clinics or not. This makes it hard to estimate how high the HIV prevalence among TB patients in Bahir Dar is.

5.8 Weight recording

Weight was recorded for almost all patients at their first visit (91.1% to 99.6%). There was no big difference between the three health facilities. In terms of their follow up, weight was recorded in less than 1/3 of the patients and in only 5.7% in Bahir Dar HC in 2002/2003 EC (2010). Han HC was the exception, with a big improvement from 2000/2001 EC (2008) to 2002/2003 EC (2010), from 0.0% to 53.5%. Weight recorded a 2nd time, was most often done no later than 2 months after. Possible reasons why this weight recording often lacked could be lack of resources or personnel, priority of other work assignments or lack of active use of this indicator in the patient follow-up. Weight loss is one of the symptoms of TB disease. In terms of following up the treatment response, weight recording is recommended for all TB patients at their first visit and after two and five months. The guidelines for weight recording is poor in the 2008 TB manual, but are improved in the new 2012 manual. Our impression after visiting FRH was that weight measurement could have easily been done for all the TB patients by using a digital scale instead of the more time consuming manually scale. This could be a step in the process of improving, in addition to the new 2012 TB manual.

5.9 The TB registrations books (based on observations)

All the TB registration books were written by hand. The handwriting could sometimes be hard to read and not all data were filled in for all patients. Missing outcome noted was one of the big problems. This contributes to poor data quality, and incorrect numbers which are reported to the authorities. Therefore, the new guidelines could be based on wrong data. Electronic recording and reporting of data will be of great help in the future.

5.10 Limitations of the study

Our data were only collected from the Ethiopian town Bahir Dar, and our results cannot be generalized for the whole country. In addition, only TB patients from Bahir Dar HC, Han HC

and FRH were included in the study. No data from TB patients from the private clinics or other smaller public health centers were collected. This makes it hard to calculate the number of TB cases diagnosed and treated in Bahir Dar during the study period.

The patient load in the two health centers were low compared to the hospital. On the other hand more than 50% of the patients in FRH were transferred out. Because no names or patient numbers were collected, and because some patients were transferred between the health facilities, there is a risk of counting the same patient twice. The feedback system between the health facilities was poor, and should be improved.

We do not speak Amharic, which was the first language for most of the health workers. Due to limited English skills for some, communication could be difficult, e.g. regarding upcoming questions about data in the TB registration books. Some patients had missing data in the registration books, like sex, age, category and outcome. For other patients, it was hard to read the handwriting. All these things make room for false numbers in our results.

Our selected time periods were based on quarters (a three month period) following the Ethiopian calendar. The exact length of one quarter varied with a few days between the health facilities and between the years. When we converted these time periods into the Gregorian calendar, a few patients might have been counted in wrong year. Data from three quarters (1st – 3rd quarter of 2001 EC) were not found among the TB registration books in Han HC. This reduced the total number of patients noted for both 2008 and 2009 from this health center.

The 2008 TB manual was not clear on how to categorize a patient with disseminated TB included ss-PTB; whether to mark the patient as ss-PTB or EPTB. “Diss TB” with no smear result noted, was written for 30 patients in the TB registration books from FRH between 2008 and 2009. Because this applied to only a few patients, we chose to categorize them all as EPTB. We do not know what category the hospital itself chose to report them as.

All our numbers were collected manually. The same was done for much of the counting and calculation of numbers for the result part. This makes a risk of small clerical errors.

We were not in close contact with the District Health Office (DHO) in Bahir Dar during our research, but supervision from this institute would probably have had a positive impact on our study. The DHO has the responsibility to follow whether DOTS is implemented according to the TB control guidelines in the three health facilities. Regular supportive supervision is expected from the DHO, and thought to improve TB control program performance.

Due to our limited experience and knowledge with TB and a study limited to three weeks in Bahir Dar, we are not able to draw any absolute conclusions about the quality of the DOTS program. Therefore, our recommendations are to be understood as humble suggestions.

6. CONCLUSION

In our study we have looked at TB registrations in the time period 2008-2010 in Bahir Dar HC, Han HC and FRH, retrospectively. Our main objective was to assess the implementation of DOTS in Bahir Dar town in means of following the national guidelines given in the standard TB manual of 2008 in Ethiopia. We generally found that they did a good job, and that they e.g. improved the TB management from 2008- 2010 in offering HIV-test to the TB patients and registering treatment outcome. The conversion rate was generally over 90% in 2010 which indicates a good follow up of ss+PTB patients. We also found some unexpected results: the amount of ss+PTB patients was low, especially at FRH (only 11% in 2010), while the numbers of EPTB patients was high (overall >40% in 2010). The HIV-prevalence was also higher than the national average of 15% in 2010; at Bahir Dar HC it was as high as 47%, but the prevalence has declined in all three health facilities. However, the overall impression is that there is room for improvements. The proportion of defaulters was too high (12% in 2010 at Bahir Dar HC) and there was no good default tracing system or a good feedback system between the health facilities. The global target for treatment success rate of 90% by 2015 was still not achieved in 2010. At FRH it was only 60%, contributed by a low registration of treatment outcome (almost 30%) and 10% deaths. The general data quality showed possibilities for improvements, as the TB registration sometimes was incomplete and inconsistent.

7. RECOMMENDATIONS

The data collection was done for almost two years ago, and improvements may have been done since our stay in Bahir Dar. Also, we are not experts on TB, but based on our results we would like to give some general suggestions that might contribute in the local improvements of the TB management.

First; regular training of health workers (including lab workers) and regular supportive supervision from the DHO is important. This should be done to keep updated on new guidelines, motivate and help implementing DOTS in the health facilities. The need of performing sputum smear examinations in correct diagnosing of TB patients and in the treatment follow-up of ss+PTB patients should be emphasized. Also, focus on default tracing and weight recording (e.g. by using quick digital scales) during the treatment is important in terms of improving treatment outcome.

Second, further operational research and international collaboration may strengthen the TB management and awareness of the existing problems both locally and in the collaborating international departments. An example may be welcoming new students from outside to engage in collaboration for developing operational research as a permanent activity in the TB program.

In the future, electronic recording and reporting of data would certainly improve the data quality and the collaboration between the health facilities concerning transfer patients.

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